K113476

DEC 16 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter	The Anspach Effort, Inc. 4500 Riverside Drive Palm Beach Gardens, FL 33410
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Date Prepared	December 13, 2011
Device Name	Dissection Tools
Classification Name	Drills, Burrs, Trephines & Accessories (Compound Powered)
Device Classification	Class II Neurological Devices Panel 21 CFR §882.4310 HBE
Predicate Devices	eMax2 Plus System (Component to system) K080802 Minimal Access Spinal Attachment (MASA) System (Component to system) K042783
Device Description	The Anspach Dissection Tools are the actual cutting devices designed exclusively for use with Anspach pneumatic or electric motor systems. These Dissection Tools are designed for surgical bone cutting and shaping procedures by trained medical/surgical personnel. Dissection Tools have a standard attachment mechanism, designed specifically for the type(s) of motors and attachments with which they will be used. The

	base materials of the Dissection Tools are tool steel, stainless steel, or carbide construction with some containing a coated layer of diamond chips. Dissection Tools are components to existing Anspach electric and pneumatic systems. The purpose of this submission is to describe a new design of the locking mechanism of the Dissection Tools. The locking mechanism provides a means to secure a Dissection Tool to the handpiece of the power system.
Indications for Use	Dissection tools are intended for cutting and shaping bone including spine and cranium.
Technological Characteristics	Dissection Tools are sterilized, individually packaged, are for single use and disposable. Dissection Tools have a standard attachment mechanism, designed specifically for the type(s) of motors both electric and pneumatic, and attachments with which they will be used. The base materials of the Dissection Tools are tool steel, stainless steel, or carbide construction with some containing a coated layer of diamond chips.
Performance Testing	Design verification was conducted on the proposed design change of the locking mechanism of the Dissection Tools. These tests include a functional approach that challenged the design output against the design requirements. The tests verified established physical characteristics, functional requirements and performance standards.
Conclusion	Based on the testing, risk analysis and comparison to the predicate devices, the Dissection Tools described in this submission perform as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

The Anspach Effort, Inc.
c/o Ms. Jeanette G. Dailey
Regulatory Affairs Manager
4500 Riverside Drive
Palm Beach Gardens, FL 33410

DEC 16 2011

Re: K113476
Trade/Device Name: Dissection Tools
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered simple cranial drills, bores, trephines, and their accessories
Regulatory Class: Class II
Product Code: HBE
Dated: November 18, 2011
Received: November 22, 2011

Dear Ms. Dailey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113476

Device Name: Dissection Tools

Indications For Use:

Dissection tools are intended for cutting and shaping bone including spine and cranium.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113476